

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	DAVID J. PARINS	Confirmation No.:	8129
Serial No.:	10/656,630	Examiner:	Jeffrey G. Hoekstra
Filing Date:	SEPTEMBER 5, 2003	Group Art:	3736
Docket No.:	1001.1674101	Customer No.:	28075
Title:	MEDICAL DEVICE COIL		

PRE-APPEAL BRIEF REQUEST FOR REVIEW ATTACHMENT

Mail Stop AF
Assistant Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

CERTIFICATE FOR ELECTRONIC TRANSMISSION

I hereby certify that this paper(s) is being electronically transmitted to the U.S. Patent and
Trademark Office on the date shown below



Thu H. Le-To

SEPTEMBER 22, 2006

Date

Dear Sir:

Applicants submit that the Examiner's rejections, as set forth in the Final Office Action mailed May 23, 2006 (hereafter "Final Office Action") and as maintained in the Advisory Action mailed August 3, 2006 (hereafter "Advisory Action"), contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* obviousness rejection. The Examiner rejected claims 1-33 under 35 U.S.C. §103(a) as being unpatentable over Richardson et al. (2001/0009980) in view of Wang et al. (6,849,224 B2). In making these rejections, the applicants respectfully submit that the Examiner has misapplied the legal standard for obviousness, contrary to relevant provisions of the MPEP and applicable case law. The pending claims are found in the Amendment mailed July 21, 2006, pages 2-8.

Among pending claims 1-33, claims 1, 9, 17, and 25 are independent, and all recite, among other elements: a helically wound coil having a plurality of windings forming a coil length; a thermoplastic polymer sleeve disposed about a portion of the coil length; and a plurality of discrete affixation points that are disposed along the coil length, wherein each discrete affixation points fixes the thermoplastic polymer sleeve to two or more coil windings, and wherein each discrete affixation points is separated from other discrete affixation points by areas where the polymer sleeve is not affixed to the coil.

One of the three basic criteria necessary to establish a prima facie case of obviousness is that the prior art references must teach or suggest all the claim limitations. (MPEP 2143). Richardson et al. and Wang et al., even if combined, fail to teach or suggest all the claim limitations. In particular, Richardson et al. and Wang et al., either alone or in combination, do not teach or suggest the plurality of discrete affixation points as recited in the claims.

The Examiner seems to indicate that Richardson et al. discloses the claimed invention “except for a plurality of discrete affixation points wherein each discrete affixation point is separated from other discrete affixation point by areas where the polymer sleeve is not affixed to the coil.” See: Page 2 of the Final Office Action. Applicants also respectfully submit that Richardson et al. does not teach or suggest that each discrete affixation point fixes the thermoplastic polymer sleeve to two or more coil windings. In any event, Richardson et al. at least does not teach or suggest a plurality of discrete affixation points as recited in the claims.

The secondary reference cited by the Examiner, Wang et al., does not cure the deficiencies of Richardson et al. in that it also fails to teach or suggest discrete affixation points as claimed. The Examiner indicated that Wang et al. teaches “intracorporal devices comprising: the application of thermal or radiation treatments to said device for configuring a plurality of discrete affixation points, as best seen in Figures 10 and 11, wherein each discrete affixation point is separated from other discrete affixation point by areas where the polymer sleeve is untreated (column 7 line 42 – column 8 line 60).” We respectfully disagree.

Wang does not teach or suggest any such “discrete affixation points”, but rather teaches the selective cross-linking of a polyethylene polymer orthopedic device to provide the device with certain desired properties. Wang et al. teaches that certain methods, such as exposure to an interrupted, masked, or pulsed radiation source, can be used to allow only

certain zones of the polymer of the orthopedic device to become cross-linked, while other zones do not become so cross-linked, resulting in a selectively cross-linked article having desired properties. See, e.g., column 2, lines 30-33, column 4, lines 61-65; column 7, lines 57-60; and column 8, lines 5-8, 13-17, and 29-35. Nothing in Wang et al. teaches or suggests that this selective cross-linking creates “affixation points” and/or fixes the polyethylene object to any other structure. Instead, Wang et al. discloses that the selective cross-linking gives the prosthetic device “desired properties”. These desired properties appear to relate to balancing such characteristics as “toughness and wear rate” in a prosthetic device. See, e.g., column 4, lines 40-57. This has nothing whatsoever to do with fixing a polymer structure to any other structure, much less creating discrete affixation points that fix a thermoplastic polymer sleeve to two or more coil windings, as claimed. Indeed, the teachings of Wang et al. suggest that the entire prosthetic device is made out of a polyethylene structure, thereby obviating any need whatsoever for the cross-linking to serve any affixing function. See, e.g., col. 2, lines 50-64, column 6, line 61 through column 7, line 13, and the Example beginning at column 9, line 64. As such, the claimed plurality of discrete affixation points that fix the thermoplastic polymer sleeve to two or more coil windings, and wherein each discrete affixation points is separated from other discrete affixation points by areas where the polymer sleeve is not affixed to the coil is not taught or suggested in Wang et al. or Richardson, either alone or in combination, and, consequently, the combination of Richardson et al. with Wang et al. fails to teach or suggest all the claim limitations. Because of this, a *prima facie* case of obviousness has not been properly established for claims 1-33, and the rejection thereof on this basis is in error.

In the Advisory Action the Examiner noted that “Wang discloses the application of pulsed irradiation to a polymer based intravascular device for controlling the localized heating of a plurality of discrete points” and that “... if the fluence of the irradiation [sic] is great enough the plurality of irradiated discrete points will mechanically bond with the workpiece below (i.e. the intravascular device).” Applicants also respectfully disagree with this portrayal of Wang et al.. Wang et al. describes methods where a prosthetic device (not an intravascular device) is formed and then selectively irradiated to incorporate and/or create the desired levels of cross-linking. See: col. 8, l. 61 – col. 9, l. 37. Further, Wang et al. discloses

that the selective or controlled cross-linking is accomplished by interrupting the exposure of the device to an irradiated beam in order to control exposure and dosage (col. 7, lines 42-48), and the irradiation sources are disclosed as including gamma rays, x-rays, electron beam or other radiation source, the units of which are indicated in Mrads. (Col. 9, lines 8-25). And again, there is no indication in Wang et al. that the disclosed methodology and/or resulting structure could be used to affix a polymer material to any other workpiece, much less to affix a polymer sleeve to two or more coil windings. Where is it taught or suggested in Wang et al. that the disclosed methodology could be used and/or result in attaching the polymer to anything else, much less be used to create a plurality of discrete affixation points as claimed?

Also in the Advisory Action, the Examiner indicated that “both Richardson et al. and Wang et al. disclose various mechanisms for configuring the mechanical properties of an intravascular device for increasing the efficacy of patient safety during advanced surgical procedures requiring the insertion of intravascular devices and specifically configuring the mechanical properties of a base metal covered in polymer and the affixation thereof.” Applicants again traverse this portrayal of at least the Wang et al. reference. Wang et al. is directed to a polyethylene prosthetic device that is selectively cross-linked to provide the prosthetic device with desired characteristics. Where in Wang does it disclose an “intravascular device”, or “specifically configuring the mechanical properties of a base metal covered in polymer and the affixation thereof”?

Again, applicants respectfully submit that Richardson et al. and Wang et al., either alone or in combination, do not teach or suggest the plurality of discrete affixation points as recited in the claims. This claim limitation is missing from the cited art, and as such, a *prima facie* case of obviousness has not been properly established.

The applicants also respectfully submit that there is no suggestion or motivation to modify the cited references or to combine the cited reference teachings to arrive at the claimed invention, and there is no reasonable expectation that such a combination would succeed at arriving at the claimed invention, and reserve the right to argue these issues on appeal. (MPEP 2143).

Reexamination and reconsideration are requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

DAVID J. PARINS

By his attorney,

Date: September 22, 2006



J. Scot Wickhem, Reg. No. 41,376
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349